

§ 226.58 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that the drug components and the Type A medicated article(s) conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications and a description of the test procedures used to check them for each kind of drug component used in the manufacture of Type A medicated article(s). This may consist of the manufacturer's or supplier's statement of specifications and methods of analyses.

(b) The establishment of specifications for Type A medicated article(s) and a description of necessary laboratory test procedures to check such specifications.

(c) Assays which shall be made of representative samples of finished Type A medicated article(s) in accordance with the following schedule:

(1) Each batch of a Type A medicated article(s) manufactured from an undiluted drug shall be assayed for its drug component(s).

(2) In the case of Type A medicated article(s) which are manufactured by dilution of Type A medicated article(s) assayed in accordance with paragraph (c)(1) of this section, each batch shall be assayed for its drug component(s) with the first five consecutive batches assaying within the limitations, followed thereafter by assay of representative samples of not less than 5 percent of all batches produced. When any batch does not assay within limitations, each batch should again be assayed until five consecutive batches are within limitations.

(d) A determination establishing that the drug components remain uniformly dispersed and stable in the Type A medicated article(s) under ordinary conditions of shipment, storage, and use. This may consist of a determination on a Type A medicated article(s) of substantially the same formula and characteristics. Suitable expiration dates shall appear on the labels of the Type A medicated article(s) to assure that the articles meet the appropriate

standards of identity, strength, quality, and purity at the time of use.

(e) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used. The official methods in "Methods of Analysis of the Association of Official Analytical Chemists,"¹ methods described in an official compendium, and any method submitted as a part of a food additive petition or new-drug application that has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.

(f) Provisions for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records shall be retained in the possession of the manufacturer and shall be maintained for a period of at least 2 years after distribution by the manufacturer of the Type A medicated article(s) has been completed.

[40 FR 14031, Mar. 27, 1975, as amended at 55 FR 11577, Mar. 29, 1990; 55 FR 23703, June 12, 1990]

Subpart D—Packaging and Labeling

§ 226.80 Packaging and labeling.

(a) Packaging and labeling operations shall be adequately controlled:

(1) To assure that only those Type A medicated article(s) that have met the specifications established in the master-formula records shall be distributed.

(2) To prevent mixups during the packaging and labeling operations.

(3) To assure that correct labeling is employed for each Type A medicated article(s).

(4) To identify Type A medicated article(s) with lot or control numbers that permit determination of the history of the manufacture and control of the batch of Type A medicated article(s).

(b) Packaging and labeling operations shall provide:

(1) For storage of labeling in a manner to avoid mixups.

¹Copies may be obtained from: Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301.